

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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THE NEW YORK TIMES COMPANY	:	
and CHRIS HAMBY,	:	
	:	
Plaintiffs,	:	
	:	<u>COMPLAINT</u>
v.	:	
	:	
UNITED STATES FOOD & DRUG ADMINISTRATION	:	
	:	
Defendant.	:	
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Plaintiffs THE NEW YORK TIMES COMPANY and CHRIS HAMBY (jointly, “The Times”), by and through their undersigned attorneys, allege as follows:

1. This is an action under the Freedom of Information Act, 5 U.S.C. § 552 *et seq.* (“FOIA”), to obtain an order for the production of agency records from the Food & Drug Administration (“FDA”) in response to a request properly made by Plaintiffs.

PARTIES

2. Plaintiff The New York Times Company publishes *The New York Times* newspaper and www.nytimes.com. The Times is headquartered in this judicial district at 620 Eighth Avenue, New York, NY 10018.

3. Plaintiff Chris Hamby is a reporter employed by The New York Times Company.

4. Defendant FDA is the agency within the federal government that has possession and control of the records that The Times seeks.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 5 U.S.C. § 552(a)(4)(B).

6. Venue is premised on The Times's place of business and is proper in this district under 5 U.S.C. § 552(a)(4)(B).

7. FOIA requires that agencies respond to FOIA requests within 20 business days. *See* 5 U.S.C. § 552(a)(6)(A).

8. Defendant FDA has failed to meet the statutory deadlines set by FOIA. *See* 5 U.S.C. § 552(a)(6)(A)–(B). Plaintiffs are therefore deemed to have exhausted all administrative remedies pursuant to 5 U.S.C. § 552(a)(6)(C).

FACTS

9. On October 18, 2022, The Times submitted two FOIA requests (together, “the Requests”) to the FDA.

10. The First Request sought “FDA’s database containing detailed information on Class II and Class III medical devices cleared through the 510(k) pathway, including data fields linking a cleared device to its predicate device(s).”

11. The Times sought expedited processing of the First Request.

12. The Second Request sought “The record layout detailing the structure of the FDA’s database on medical devices cleared through the 510(k) pathway.” The Second Request added, “It would contain information including a list and description of the fields in the database, as well as supporting documentation needed to understand the data and how multiple tables in a relational database can be joined. For clarity: This request is for documentation of the database’s structure, not the underlying data itself.”

13. The Times sought expedited processing of the Second Request.

14. On October 19, 2022, the FDA acknowledged receipt of the First Request and assigned the request control number: 2022-7512.

15. On October 19, 2022, the FDA acknowledged receipt of the Second Request and assigned the request control number: 2022-7511.

16. On October 19, 2022, the FDA denied The Times's requests for expedited processing for both Requests, stating that The Times had established neither "a compelling need that involves an imminent threat to the life or physical safety of an individual" nor "that there exists an urgency to inform the public concerning actual or alleged Federal Government activity."

17. On December 20, 2022, The Times emailed the FOIA officer in the FDA's Center for Devices and Radiological Health ("CDRH") seeking a status update on the Requests.

18. On January 4, 2023, The Times received an email from the CDRH FOIA officer stating that processing both requests would take 18 to 24 months.

19. The Times responded on January 4, 2023 asking the agency to elaborate on why the Second Request was placed in the complex processing track, given that it is a "relatively simple request ... just for the record layout of a database."

20. The CDRH responded on January 5, 2023, "The 18-24 month estimate is due to processing requests in the queue that were filed before your requests in addition to your request."

21. The Times has received no further response to the Requests.

CAUSE OF ACTION

22. The Times repeats, realleges, and reincorporates the allegations in the foregoing paragraphs as though fully set forth herein.

23. Defendant is an agency subject to FOIA and must therefore release in response to a FOIA request any disclosable records in its possession at the time of the request and provide a lawful reason for withholding any other materials as to which it is claiming an exemption.

24. Defendant has failed to meet the statutory deadlines set by FOIA. 5 U.S.C. § 552(a)(6)(A)–(B). Accordingly, The Times is deemed to have exhausted its administrative remedies under FOIA.

25. Defendant is permitted to withhold documents or parts of documents only if one of FOIA's enumerated exemptions apply.

26. No exemptions permit the withholding of the documents sought by the Requests.

27. Accordingly, Plaintiffs are entitled to an order compelling Defendant to produce the records responsive to the Requests.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court:

28. Declare that the documents sought by the Requests, as described in the foregoing paragraphs, are public under 5 U.S.C. § 552 and must be disclosed;

29. Order Defendant to undertake an adequate search for the requested records and provide that record to Plaintiffs within 20 business days of the Court's order;

30. Award Plaintiffs the costs of this proceeding, including reasonable attorneys' fees, as expressly permitted by FOIA; and

31. Grant Plaintiffs such other and further relief as this Court deems just and proper.

Dated: New York, NY
February 6, 2023

/s/ David E. McCraw

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